

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CYDEX PHARMACEUTICALS, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 19-956 (LPS) (JLH)
)	
ALEMBIC GLOBAL HOLDING SA,)	
ALEMBIC PHARMACEUTICALS, LTD. and)	
ALEMBIC PHARMACEUTICALS, INC.,)	
)	
Defendants.)	

CONSENT JUDGMENT AND DISMISSAL ORDER

This action for patent infringement (the “Litigation”) has been brought by Plaintiff CyDex Pharmaceuticals, Inc. (“CyDex” or “Plaintiff”) against Defendants Alembic Global Holding SA, Alembic Pharmaceuticals, Ltd. and Alembic Pharmaceuticals, Inc. (collectively, “Alembic”) for infringement of United States Patent Nos. 8,410,077, 9,200,088, and 9,493,582 (collectively, the “CyDex Patents”). CyDex’s commencement of the Litigation was based on its receipt of notice from Alembic that Alembic had filed Abbreviated New Drug Application (“ANDA”) No. 212810 with the United States Food and Drug Administration (“FDA”) containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) directed to the CyDex Patents and seeking approval to market a generic melphalan hydrochloride product at a strength of 50 mg (free base)/vial as a powder for injection prior to the expiration of the CyDex Patents.

CyDex and Alembic have agreed to enter into a final settlement agreement regarding this Litigation (“Settlement Agreement”). The Court, upon the consent and request of CyDex and Alembic, hereby acknowledges the following Consent Judgment and, upon due consideration, issues the following Dismissal Order.

CyDex and Alembic now consent to this Consent Judgment and Dismissal Order and IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. Subject matter jurisdiction, personal jurisdiction, and venue solely with respect to the Litigation are all proper in this Court.

2. In this Litigation, CyDex has charged Alembic with infringement of the CyDex Patents in connection with Alembic's submission of ANDA No 212810 directed to a melphalan hydrochloride product at a strength of 50 mg (free base)/vial as a powder for injection to the FDA.

3. In response to CyDex's charges of patent infringement, Alembic has alleged certain defenses and counterclaims. No decision has been obtained by the parties from this Court regarding these charges of infringement or these defenses and counterclaims.

4. Alembic has infringed the CyDex Patents pursuant to 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 212810 before the expiration of the CyDex Patents.

5. All claims, counterclaims, and affirmative defenses presented by CyDex as between it and Alembic, or by Alembic, in the Litigation are hereby dismissed without prejudice and without costs, disbursements or attorneys' fees.

6. Alembic, its Affiliates, officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them shall not engage in manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any generic melphalan hydrochloride products that are the subject of ANDA No. 212810 ("Alembic's ANDA Product") until such date permitted by the Settlement Agreement that the Parties have entered into.

7. Nothing herein prohibits Alembic or its Affiliates from maintaining a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) or pursuant to 21 C.F.R. § 314.94(a)(12) with respect to the CyDex Patents.

8. Nothing herein restricts or is intended to restrict the U.S. Food and Drug Administration from approving ANDA No. 212810.

9. Neither this Consent Judgment and Dismissal Order nor the entry of this Consent Judgment and Dismissal Order may be asserted by CyDex against Alembic or any of its Affiliates, and shall have no preclusive effect whatsoever, in any cause of action, litigation or proceeding with respect to any product other than Alembic's ANDA Product in the United States or with respect to any patent other than the CyDex Patents.

10. For purposes of this Consent Judgment, the term "Affiliate" shall have the meaning set forth in the Settlement Agreement.

11. CyDex and Alembic each expressly waives any right to appeal or otherwise move for relief from this Consent Judgment and Dismissal Order.

12. Compliance with this Consent Judgment may be enforced by the Parties and their successors in interest, or assigns, as permitted by the terms of the Settlement Agreement.

13. This Court retains jurisdiction over CyDex and Alembic for purposes of enforcing this Consent Judgment and Dismissal Order as well as any dispute regarding the Settlement Agreement.

14. The Clerk of the Court is directed to enter this Consent Judgment and Dismissal Order forthwith.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

Attorneys for Plaintiff

BENESCH FRIEDLANDER COPLAN & ARONOFF LLP

/s/ Kevin M. Capuzzi

Kevin M. Capuzzi (#5462)
Kate Harmon (#5343)
Noelle B. Torrice (#5957)
222 Delaware Avenue, Suite 801
Wilmington, DE 19801
(302) 442-7010
kcapuzzi@beneschlaw.com
kharmon@beneschlaw.com
ntorrice@beneschlaw.com

Attorneys for Defendants

June 4, 2021

SO ORDERED this ^{10th} day of June, 2021.



The Honorable Leonard P. Stark